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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,060	07/25/2003	Sarah Maillefer	2652	4150
7590 08/05/2008 STRIKER, STRIKER & STENBY 103 East Neck Road Huntington, NY 11743				
EXAMINER VAKILL, ZOHREH				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
08/05/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/628,060

Applicant(s)

MAILLEFER ET AL.

Examiner

ZOHREH VAKILI

Art Unit

1614

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claims 1-18 and 25-32 are presented for examination.

Applicant's Amendment filed March 27, 2008 has been received and entered into the present application. Claims 1-18 are withdrawn, and claims 25-32 are pending and are herein examined on the merits.

Applicant's arguments, filed March 27, 2008 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph (New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-32 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an Enablement rejection.

The specification does not reasonably provide enablement for the product to be more sticky to the function of time. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. *PPG v. Guardian*, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the nature of the invention;
- 2) the breadth of the claims;

- 3) the predictability or unpredictability of the art;
- 4) the relative skill of those in the art,
- 5) the amount of direction or guidance presented;
- 6) the presence or absence of working examples;
- 7) the quantity of experimentation necessary;
- 8) the state of the prior art.

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

- 1) the nature of the invention; the invention is directed to a method of shaping or styling hair in a hairstyle, said method comprising the steps of: a) providing a hair wax composition; b) applying said hair wax composition to the dry or slightly wet hair to be shaped; c) within an initial time interval immediately after the applying of step b) in which said hair wax applied to the hair is more sticky than during a time after said initial time interval, putting the dry or slightly wet hair to be shaped into said hairstyle.
- 2) the breadth of the claims; the scope of the method claims include a method of shaping or styling hair in a hairstyle in which said hair wax composition applied to the hair is more sticky than during a time after said initial time interval. The claims are broad and unclear as the composition is more sticky when initially applied and what is the time interval that the composition becomes less sticky, and how the composition becomes less sticky.
- 3) the predictability or unpredictability of the art; the art does not enable a

person of ordinary skill in the art to make and use the claimed invention without resorting to undue experimentation. The burden of enabling one skilled in the art to a method of shaping or styling hair in a hairstyle in which said hair wax composition applied to the hair is more sticky than during a time after said initial time interval. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of the composition being more sticky than during a time after said initial time interval. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients to be more sticky or less sticky due to the function of time. Even more so the support for unpredictability of the composition being more sticky than during a time after said initial time interval is supported by the references Patent No. 4970067 and Patent No. 6294159.

No experimental evidence or mechanism of action for supporting the composition applied to the hair is more sticky than during a time after said initial time interval using the specified actives by simply administering, by any method, an amount of the claim specified active agents. The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for shaping or styling hair in a hairstyle providing a hair wax composition. It is unpredictable to practice with the hair wax composition for shaping hair in a hairstyle as instantly claimed. The specification is viewed as lacking an adequate enablement of where the hair wax composition applied to the hair is

more sticky than during a time after said initial time interval.

4) the relative skill of those in the art; the relative skill of those in the art of cosmetics is high.

5) the amount of direction or guidance presented; the specification and the example does not provide any guidance in terms of how the hair wax composition is more sticky when initially applied . The specification provides no direction for ascertaining, how the composition becomes less sticky and what is the time interval.

6) the presence or absence of working examples; no working examples are provided for the hair wax composition when applied to the hair to be more sticky during a time after said initial time interval, for example in a person, in the specification. The applicant has not provided any competent evidence or disclosed any tests that are highly predictive for the effects of the instant composition. Applicant has provided no analysis of the test results in the specification as none of the examples determine stickiness increase as required in the instant claims. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

7) the quantity of experimentation necessary; the quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention and unpredictability of the hair wax composition, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims. The lack of adequate guidance from the specification or prior art with regard to the actual treatment fails to rebut the presumption of unpredictability present in this art. Applicants fail to provide the guidance and information required to ascertain which particular hair style the claimed agent will be effective against without resorting to undue experimentation. Applicant's limited disclosure of the hair wax composition is not sufficient Applicant must enable a representative set of hairstyles.

In consideration of each of factors 1-7, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Conclusion

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner

July 18, 2008

1614

Art Unit: 1614

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614